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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,816	08/25/2000	Michael R. Yeaman	660081.415C1	6324

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/21/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/648,816

Applicant(s)

YEAMAN ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 67-79 is/are pending in the application.
- 4a) Of the above claim(s) 70-74 and 76-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-69 and 75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) ✓
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20 ✓
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 67-79 are pending.

Applicants' amendment filed on May 09, 2003 (Paper No. 22) is acknowledged, and applicants' response has been fully considered. Claim 67 has been amended, and claims 70-74 and 76-79 are non-elected inventions, thus withdrawn from consideration. Therefore, claims 67-69 and 75 are examined.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claim 67 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to an antimicrobial peptide. As written, the claim does not explicitly indicate the hand of man. Insertion of "isolated" or "purified" in connection with antimicrobial peptide is suggested. See MPEP § 2105. Claims 68, 69 and 75 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 67-69 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 67-69 and 75 are indefinite because of the use of the term "mimetics thereof".

The term "mimetics thereof" renders the claim indefinite, it is unclear what structures the mimetics have, and how different the mimetic is from the parent peptide. Claims 68, 69 and 75 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

In response, applicants indicate the claim has been amended to cite "mimetics thereof" instead of "derivatives thereof", and the term "derivatives thereof" is definite in view of the specification, which discloses the invention peptide can be conformationally stabilized by replacing selected amino acid in the original peptide chain with amino acids that restrict the motion of the peptide chain, e.g.,  $\beta$ -branched, N-methyl,  $\alpha$ ,  $\beta$ -dehydro,  $\alpha$ ,  $\alpha$ -dialkyl and D-amino acids, and the substitutions with D- and other unusual amino acids into peptide templates can extend the half-life of the invention peptide (page 42, lines 12-21), and a derivative of an invention peptide can also include non-amide linkage between amino acids, amino acid analogs and other mimetics, where mimetics include peptidomimetics, peptoids or other peptide-like polymers such as  $\beta$ -amino acids or other non-polymeric compounds (pages 3-5 of the response). The response is not found persuasive because the specification indicates various substitutions can be made in the peptide as to "mimetics thereof", however, the claim does not specify which amino acid is substituted, and what group is used for substitution, thus it is not clear what structures the mimetics would have.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 67-69 and 75 are rejected under 35 U.S.C. 102(b) as anticipated by Darveau *et al.* (U. S. Patent 5,409,898, April, 1995).

Darveau *et al.* disclose a cationic oligopeptide such as Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly which has  $\alpha$  helical amphiphilic structure and antibacterial activity (column 12, lines 31-32 and 49-54), this peptide is the mimetic of SEQ ID NO:3 (Ala-Leu-Tyr-Lys-Lys-Phe-Lys-Lys-Lys-Leu-Leu-Lys-Ser-Leu-Lys-Arg-Leu-Gly; claims 67-69) or SEQ ID NO:9 (Ala-Leu-Tyr-Lys-Lys-Trp-Lys-Asn-Lys-Leu-Leu-Lys-Ser, where the underline indicates the different residue from the sequence cited in the reference; claim 75) that retains antimicrobial activity. Since the claim does not define the “mimetics thereof”, any substituted peptide which retains antimicrobial activity would meet the criteria of the claim.

4. Claims 67 and 68 are rejected under 35 U.S.C. 102(b) as anticipated by Kupsch *et al.* (The EMBO Journal 12, 641-650, 1993).

Kupsch *et al.* disclose one member of variable opacity (Opa) outer membrane proteins, OPA 65 has 236 amino acids and comprises a sequence of ARYRKWK, which is the same as the core sequence of the claimed invention (Fig. 4; see sequence match; claims 67 and 68). The OPA 65 protein would be expected to have antimicrobial activity because it contains the same core sequence as the claimed invention.

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**Conclusion**

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CYK*  
Patent Examiner

*Christopher S. F. Low*

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July 16, 2003

CHRISTOPHER S. F. LOW  
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